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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,856	03/21/2002	Andrew Austen Mortlock	Z70598-1	6741
28120	7590	02/12/2004	EXAMINER	
ROPEs & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,856	MORTLOCK ET AL.	
	Examiner	Art Unit	
	Duc Truong	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: ____ . |

DETAIL ACTION

1. The disclosure is objected to because of the following informalities:
 - a. Unmatched parentheses are found on the following pages, and lines:
 - i. Page 6, lines 10 and 16;
 - ii. Page 7, line 29;
 - iii. Page 10, line 9;
 - iv. Page 11, line 16;
 - v. Page 12, line 23;
 - vi. Page 21, line 25;
 - vii. Page 40, line 24;
 - b. Misspelled words are found on the following pages and lines:
 - viii. Page 5, line 18, the misspelled word is “hetercycl”;
 - ix. Page 19, line 15, the misspelled word is “heterocycl”.

Appropriate correction is required. Applicant is advised to review thoroughly the specification for other informalities as well.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2-4, 9, 10, 12, 16, 17, 22, 24, 26, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- c. Claims 2-4 recite the limitation of “cycloalkynyl”, which suggests a ring with a triple bond. Such a ring is not known to exist since the presence of a triple bond would cause bond stress and strain, which in turn would cause instability in the ring. Claim 2 also has a misspelled word, “hetercyclyl”.
- d. Claim 9 recites the limitation of “polar group” which is not recited in any of the preceding claims. It is unclear if the limitation, “polar group”, includes only substituents on claim 2, or more.
- e. Claim 10, in the definition of R⁹, the limitation of “methylene” suggests a divalent group (i.e., -CH₂-) which is not possible for a terminal group since the carbon would have an incomplete valence.
- f. Claim 12 recites “formula (1), (3), (6), or (10)” which is not recited in claim 5. Perhaps, applicant means “group”. Note, in claim 5, group (1) includes “hydrogen” and “C₁₋₅alkyl”, which are not considered as a “formula”.
- g. Claims 16 and 17 recite the definition of R⁸⁰ to include the limitation of “a large substituent of a chain of at least 4 atoms” which has indefinite metes and bounds because it is not clear if said limitation includes amino acids? Fatty acids? Proteins? Sequences? Or polymer resin?
- h. Claim 23 recites the limitation of “R¹⁰⁰ is a group R⁷⁰”, which is not recited in claim 20. Note, in claim 20, the scope of R¹⁰⁰ is not the same as that of R⁷⁰.
- i. Claim 26 recites the phrase “converting a group...to a group...respectively or to a different such group”, which is unclear as to which functional group is converted into which, and what is meant by “a different such group”.

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j. Use claim: Claim 28 provides for the use of a compound according to any one of claims 1 to 25, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 28 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

h. Claim 30 is a substantial duplicate of any one of claims 1-25 since the preamble “for use in therapy” does not result in a structural change.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Scope of Enablement:** Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation and use of formula I wherein the hydrocarbyl group is alkyl, alkenyl, alkynyl, cycloalkyl, or cycloalkenyl group, etc., but does not reasonably provide enablement for the preparation and use of those compounds wherein the hydrocarbyl is cycloalkynyl group. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .The scope the term “hydrocarbyl” includes cycloalkynyl group which has a triple bond in the ring. Such a ring is not stable, and is not known to exist. The state of the art does not teach the preparation and use of a compound having a cycloalkynyl ring. The specification does not provide any guidance for the preparation and use of a compound having a cycloalkynyl group. Thus, with the unpredictable nature in the art, and limited guidance, the skilled chemist would have to carry out undue experimentation to } make and use compounds of formula I having a cycloalkynyl group.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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4. Claims 1-7, 10, 12-15, 26, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Uckun et. al. (US 6,258,820). Uckun et. al. lists compound P-133 on columns 29 & 30, also compound P-215 on columns 33 & 34. Those two compounds read on the instant formula (I) with the following substituents:

X is NR⁶ wherein R⁶ is hydrogen;

R⁵ is pyridyl or pyrimidyl;

R¹ and R⁴ are hydrogen atoms;

R² and R³ are R⁹X¹ wherein X¹ is -O- while R⁹ is hydrocarbyl or alkyl;

The generic preparation of said compounds is described in Scheme 2 on column 10, which also reads on the process recited in claim 26. Said compounds also have pharmaceutical use, and thus teaching of Uckun et. al. anticipates the composition claims as well.

Claim Objections

5. Claims 5, 6, and 20 are objected for the following informalities:

- j. Claim 5 has an unmatched parenthesis on page 194, line 1;
- k. Claim 6 has an unmatched parenthesis on page 196, line 7;
- l. Claim 20 recites a misspelled word "hetercycyl". Also in claim 20, variable p" is not legible on the formula.

6. Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternatives. See MPEP § 608.01(n). Accordingly, the claim 19 has not been further treated on the merits. Claim 19 is dependent on claims 2 or 3, and any one of claims 14-18.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9 am - 5:30 pm) starting from January 12th, 2004.

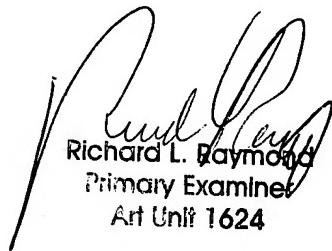
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

February 2, 2004



Richard L. Raymond
Primary Examiner
Art Unit 1624